UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,191	07/30/2003	Richard D. Paoletti	DE-1495	9822

1109 7590 08/02/2006

ANDERSON, KILL & OLICK, P.C.
1251 AVENUE OF THE AMERICAS
NEW YORK,, NY 10020-1182

EXAMINER	
HUYNH, LOUIS K	
ART UNIT	**PAPER NUMBER**
3721	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,191	PAOLETTI, RICHARD D.	
	Examiner	Art Unit	
	Louis K. Huynh	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/19/2006 has been entered.

Claim Objections

2. Claims 27 and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation of the warning statement and other distinguishing characteristics being on the seal is already present in claim 1 from which claims 27 depends, and is already present in claim 13 from which claim 29 depends.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the reference character "22" which is not mentioned in the description. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing

date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of the perforated lines being located on portions of the seal that require the visual attention of a preparer so that the preparer is forced to look at the warning statement and other distinguishing characteristics is not supported by the specification and/or the drawings. Note that FIG. 4 shows perforated lines (19) are located on a portion of the heat-shrink cover (10) where the "warning" labels (20) and other distinguishing characteristic (22) do not occupy, and no where in the specification teaches such claimed limitation.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 25, 26, 28 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 25, lines 3-4: "including a portion of the closure of the container and a portion of the closure" is confusing.
- Claim 26, lines 10-11: "including a portion of the closure of the container and a portion of the closure" is confusing.
- Claims 28 and 30 are indefinite because the perforated line being located on portions of the seal that require the visual attention of a preparer so that the preparer is forced to look at the warning statement and other distinguishing characteristics is not supported by the originally filed specification and drawings.
- Claim 31, lines 4-5: "including a portion of the closure of the container and a portion of the closure" is confusing.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 13-19, 21, 23-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Key (US 6,385,878).

With respect to claims 1 and 27, Key discloses a safety seal comprising a heat-shrink plastic cover (100) that is adapted to be placed over a medicine container (130), wherein the

heat-shrink plastic cover is provided with a written indicia (114) such as product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container.

With respect to claims 13 and 29, Key discloses a safety seal method including the steps of: placing a heat-shrink plastic cover (100) over a medicine container (130), applying heat to shrink the heat-shrink plastic cover (100) to cover the medicine container (130) and to form a safety seal (col. 5, lines 18-20), providing the heat-shrink plastic cover (100) with a written indicia (114) such as product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container.

With respect to claims 2 and 14, the heat-shrink plastic cover (100) is provided with a set of perforated lines (116 & 118) (FIG. 3).

With respect to claims 3 and 15, Key teaches in another embodiment that the heat-shrink plastic cover (100) is provided with a set of perforated lines (704a, 704b) that are configured as a pull tab (FIG. 7).

With respect to claims 4 and 16, Key teaches in another embodiment that the heat-shrink plastic cover (100) is provided with a set of perforated lines (604a, 604b) that are configured as a tear strip (FIG. 6).

With respect to claims 5 and 17, the written indicia (114) can include product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container prior to removing the heat-shrink plastic cover (100).

With respect to claims 6 and 18, the heat-shrink plastic cover (100) includes visual cues such as the written indicia (114) and tactile awareness such as the texture of the heat-shrink plastic cover and/or the edge of the heat-shrink plastic cover disposed on top of the medicine container closure.

With respect to claims 7, 8, 19 and 21, the container (130) is a vial and is configured as a bottle shaped container.

With respect to claims 11 and 23, the heat-shrink plastic cover (100) covers the medicine container's mouth as shown in FIGS. 3, 6, and 7.

With respect to claims 12 and 24, the texture of the heat-shrink plastic cover and/or the edge of the heat-shrink plastic cover would provide a tactile awareness of the heat-shrink plastic cover being in place.

With respect to claims 25 and 31, the heat-shrink plastic cover (100) covers the container (130) including a portion of the closure (132) as shown in FIG. 3; and the heat-shrink plastic cover (100) is provided with perforated lines (116 & 118) that are configured to remove the heat-shrink plastic cover completely from the closure (132) as shown in FIGS. 4 & 5.

With respect to claim 26, Key discloses a safety seal comprising a heat-shrink plastic cover (100) that is adapted to be placed over a medicine container (130), wherein the heat-shrink plastic cover is tubular (col. 4, lines 5-8), transparent (col. 4, line 32-33), and provided with a written indicia (114) such as product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container. The heat-shrink plastic cover (100) is configured to cover the container (130) including a portion of the closure (132) as shown in FIG. 3; and the

heat-shrink plastic cover (100) is provided with perforated lines (116 & 118) that are configured to remove the heat-shrink plastic cover completely from the closure (132) as shown in FIGS. 4 & 5.

With respect to claims 28 and 30, FIG. 3 of the Key reference shows perforated line (116) being located at a location on the heat-shrink plastic cover (100) such that a person when looks for the perforated line would see the written indicia (114) disposed on the heat-shrink plastic cover (100).

With respect to claim 32, Key discloses a safety seal method including the steps of: placing a tubular (col. 4, lines 5-8) and transparent (col. 4, line 32-33) heat-shrink plastic cover (100) over a medicine container (130), applying heat to shrink the heat-shrink plastic cover (100) to cover the medicine container (130) and to form a safety seal (col. 5, lines 18-20), providing the heat-shrink plastic cover (100) with a written indicia (114) such as product name, ingredient or directions for use (col. 4, lines 13-20), which would alert and enable the user to distinguish the medicine in the container (130) from other medicine in a different container. The heat-shrink plastic cover (100) is configured to cover the container (130) including a portion of the closure (132) as shown in FIG. 3; and the heat-shrink plastic cover (100) is provided with perforated lines (116 & 118) that are configured to remove the heat-shrink plastic cover completely from the closure (132) as shown in FIGS. 4 & 5.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Key (US 6,385,878).

The method and the heat-shrink plastic cover of Key meets all of applicants claimed subject matter but lack the specific teaching of the medicine container being configured as an intravenous bag. However, intravenous is a solution to be administered in to living body and thus the intravenous bag having outlet port that must be labeled with written indicia and must be protected from tampering; therefore, it would have been obvious to a skilled person in the art, at the time of the invention, to have modified the method of Key by having placed the heat-shrink plastic cover over an intravenous bag having outlet port, as required, so that the user can be informed of the integrity of the intravenous bag prior to usage.

12. Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Key (US 6,385,878) in view of Novice et al. (US 5,205,827).

The method and the heat-shrink plastic cover of Key meets all of applicants claimed subject matter but lack the specific teaching of the medicine container being configured as a syringe. However, Novacek teaches that medical syringe must be protected in a sterile condition such as wrapping the syringe with heat-shrink plastic cover (308) that serve as a tamperproof (FIG. 55) and assist in maintaining the sterility of the syringe (col. 28, line 56 – col. 29, line 8). Therefore, it would have been obvious to a skilled person in the art, at the time of the invention, to have modified the method of Key by having placed the heat-shrink plastic cover over a

syringe, as taught by Novacek, in order to provide tamperproof and to assist in maintaining the sterility of the syringe.

Response to Arguments

13. Applicant's arguments filed 07/19/2006 have been fully considered but they are not persuasive.

- Applicant contends that the reference to Key (US 6,385,878) teaches away from a warning statement that is essentially "in the face" of the preparer when the seal is removed because the label in Key can rotate rather than being placed in a position where the warning statement is in front of the eyes of the preparer. This is not found persuasive because Key discloses in FIG. 3 an embodiment of the heat-shrink plastic cover (100) forming a safety seal that is provided with a perforated line (116) for the removal of the safety seal, wherein a preparer while looking for the perforated line (116) in attempting to remove the seal would face the written indicia (114) which clearly states the name of the medicine container which differentiates the medicine container from other medicine containers. Furthermore, the fact that the heat-shrink plastic cover (100) of Key being rotatable with respect to the medicine container 9130) does not alter the location of the perforated line (116) with respect to the written indicia (114); therefore, the preparer still faces the written indicia (114) when looking for the perforated line (116).
- Applicant contends that the reference to Key (US 6,385,878) does not address providing multiple alerts visual, tactile and functional to the provider in the process of medication administration and drawing the provider's special attention to these products. This is not found persuasive because the safety seal of Key having written indicia (114) such as

product name, ingredient or direction for use, which alerts and enables the user to distinguish the medicine in the container from other medicine in a different container, and thus the safety seal of Key satisfies all of the claimed limitation.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is 571-272-4462. The examiner can normally be reached on M-F from 8:00AM to 3:00PM.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louis K. Huynh
Primary Examiner
Art Unit 3721

July 27, 2006